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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/321,179	10/11/1994	WALTER P. CARNEY	40441CZJPWNP	1590
7590	06/30/2004		EXAMINER	
JOHN P. WHITE COOPER AND DUNHAM 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10112			HOLLERAN, ANNE L	
		ART UNIT	PAPER NUMBER	
			1642	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/321,179	CARNEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 April 2004.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. The amendment filed April 1, 2004 is acknowledged. Claim 19 was amended.
2. Claim 19 is pending and examined on the merits.

***Claim Rejections Withdrawn:***

3. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

***Claim Rejections Maintained:***

4. The rejection of claim 19 under 35 U.S.C. 102(e) as being anticipated by Hudziak (US Patent 6,015,567) or Ring (US Patent 6,054,561) is maintained for the reasons of record.

Claim 19 is drawn to a substantially purified extracellular domain of the human neu gene product that is detectable in a biological fluid by monoclonal antibody OD-3, NB-3 or TA-1. The detectability of the extracellular domain of the human neu gene product, or of the entire human neu gene product, by any of these monoclonal antibodies is considered to be an inherent property of the extracellular domain of the human neu gene product. Because the claim lacks a transitional phrase and also because of the lack of antecedent basis for "said product", the claim reads on a polypeptide that is either the extracellular domain of, or the entire human neu gene product.

Applicants' arguments have been carefully considered but are unpersuasive. Applicant argues that because neither Hudziak nor Ring teaches immunoreactivity with the specific monoclonal antibodies listed in the claim, that neither reference teaches the claimed invention. This is not persuasive because immunoreactivity with the specific monoclonal antibodies is an inherent property of the extracellular domain and therefore, the art does not need to explicitly teach this limitation.

Hudziak teaches a polypeptide that is the extracellular domain of a neu related gene product and that has a molecular weight from about 95,000 daltons to about 115,000 daltons (see for example, column 1, lines 15-20, column 6, line 55-column 7, line 6, and figure 12 (including description)). Ring teaches a composition comprising the human neu related protein that comprises the extracellular domain of a neu related gene product and which has a molecular weight from about 95,000 daltons to about 115,000 daltons (see for example, abstract, column 5, lines 24-40, and column 27, lines 1-40). Therefore, Hudziak or Ring teaches the claimed invention.

5. The rejection of Claim 19 under 35 U.S.C. 102(b) as being anticipated by either Yamamoto (Nature, 319: 230-234, 1986; cited in an IDS) or Coussens (Science, 230: 1132-1139, 1985; cited in an IDS) is maintained for the reasons of record.

Applicants' arguments have been carefully considered but are unpersuasive. Applicant argues that because neither Yamamoto nor Coussens teaches immunoreactivity with the specific monoclonal antibodies listed in the claim, that neither reference teaches the claimed invention. This is not persuasive because immunoreactivity with the specific monoclonal antibodies is an

inherent property of the extracellular domain and therefore, the art does not need to explicitly teach this limitation.

Yamamoto teaches the human c-erb-B2 polypeptide and teaches the extracellular domain (see abstract, page 233, fig. 4, and page 233, 1<sup>st</sup> col.). Coussens teaches the human neu gene product (Figure 1), and teaches the extracellular domain (page 1133, 2<sup>nd</sup> to 3<sup>rd</sup> col.). Therefore, either Yamamoto or Coussens teaches the claimed invention.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1642

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran

Patent Examiner

June 28, 2004

*AMHarris*  
ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER  
6/28/2004